REMARKS

Claims 1-7, 9-26, 34 and 35 were pending in this application. Claims 1, 5 and 26 are amended. Support for the amendment to claim 1 may be found throughout the specification as originally filed, for example, at least on page 11, lines 36-38; page 21, lines 1-12; page 22, lines 10-12; and page 29, lines 1-10. Claim 5 is amended to comply with the election of species requirement (as discussed below). Claim 26 is amended to clarify the subject matter being claimed. Support for the amendment to claim 26 may be found throughout the specification and claims as originally filed, for example, at least on page 34, lines 8-33.

No new matter is introduced by the foregoing amendments. After entry of this Amendment, **claims 1-7, 9-26, 34 and 35 are pending in this application**. Examination of the pending claims is requested.

Response to Restriction Requirement

Claims 1-35 of this §371 National Stage application were indicated as being subject to a restriction requirement. In particular, the following Groups have been designated:

Group I (claims 1-7 and 9-19)	Drawn to a detection method of analyzing a tissue sample.
Group II (claims 20-26 and 34-35)	Drawn to a method of screening for disease.

The Office action states that "Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features…" Groups I and II do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, Applicants traverse the restriction requirement. Applicants request that the requirement be withdrawn in light of the amendments and arguments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a national stage application such as this. Unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "[t]he expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

This makes it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are linked to form a single inventive concept? If there is, then one asks does that special technical feature **define a contribution over the prior art** for each of the claimed inventions? If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

The restriction requirement between Groups I and II is improper because Group I and Group II are linked to form a single general inventive concept as required under 37 CFR § 1.475 (or PCT Rule 13.1). Groups I and II share at least the technical feature of an active moiety which acts within or upon the target cells or components within the sample to generate a detectable signal or product through modification of the target cells or components. This technical feature is not described in the cited art. Therefore, Applicants respectfully ask the Examiner to withdraw the restriction requirement because Group I and Group II are linked by a shared technical feature that was not previously disclosed by the cited art and thus, they form a single general inventive concept under 37 CFR § 1.475.

In summary, as required by 37 CFR § 1.475, the claims pending in the application have unity of invention because they are directed "to a group of inventions so linked as to form a

single general inventive concept" and because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature" – an active moiety which acts within or upon the target cells or components within the sample to generate a detectable signal or product through modification of the target cells or components – and this special technical feature "define[s] a contribution . . . over the prior art."

Since unity of invention exists between Groups I and II in the present application, it is inappropriate to subject the claims to a requirement for restriction. Applicants request that the requirement be withdrawn, that the Groups be rejoined, and that all of the claims be examined in the current case.

Additional remarks

Applicants also traverse the restriction requirement at least, in part, because claim 26 has been improperly placed into Group II. Claim 26 depends from claim 1 and is directed to a method of analyzing a tissue sample that is done by automation. Therefore, claim 1 is directed to a method of analyzing a tissue sample and belongs with Group I. Applicants respectfully request that claim 26 be rejoined with Group I claims and be examined with Group I.

Election

Under protest, Applicants elect the alleged invention of Group I (claims 1-7, 9-19 and 26, as discussed above). Upon the election of Group I, the Office further alleges that "[t]his application contains claims directed to more than one species of the generic invention." Election of one of each alleged species is required. Applicants elect the following species:

Type of targeting moiety:	Antibody binding domain
Type of detectable product:	Iodinated tryptophan or tyrosine
Type of active moiety:	Lactoperoxidase
Type of target component in the sample:	Receptor protein

With regard to the species elections, Applicants thank the Examiner for acknowledging (at page 5 of the Office action) that "[u]pon the allowance of a generic claim, applicant will be

entitled to consideration [in the present application] of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR §1.141." Claims 1-2, 9-11, 16 and 18 are noted as being generic.

Finally, the Office requires the "reply must also identify the claims readable on the elected species, including any claims subsequently added" (page 5 of the Office Action). Claims 1-3, 5, 12-19, and 26 read on the elected species.

In accord with 37 CFR §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement reconsidered, if it is maintained in spite of this response.

CONCLUSION

Substantive examination of the pending claims is respectfully requested. The Examiner is invited to call the undersigned if the Examiner believes that a telephone interview would facilitate substantive examination of this application.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Karri Kuenzli Bradley/
Karri Kuenzli Bradley, Ph.D.
Registration No. 56,300